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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,104	02/14/2006	Ivan Kamiel De Scheerder	DCB-06-1060	2612

35811 7590 12/21/2010

IP GROUP OF DLA PIPER LLP (US)
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER	
GANESAN, SUBA	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
12/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,104	DE SCHEERDER ET AL.	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,8,9 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8,9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/25/2010 has been entered.

Response to Arguments

2. Applicant's claim and specification amendments filed 5/25/2010 are considered to add new matter into the disclosure, consequently a specification objection and a rejection under 35 U.S.C. § 112, first paragraph have been applied.

3. Applicant's arguments with respect to claims 1, 4-6, 8-9 and 15 have been considered but are moot in view of the new ground(s) of rejection.

Specification

4. The amendment filed 5/25/2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In amended para. 26, line 6: "free from a biocompatible coating" is not supported by the original disclosure. Although the specification discloses direct drug coating onto the stent (para. 31) this

discussion is limited to adding the drug to polymer free stents and is entirely silent as to the stent being "free from a biocompatible coating".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-6, 8-9 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, line 3: "free from a biocompatible coating" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Although the specification discloses direct drug coating onto the stent (para. 31) this discussion is limited to adding the drug to polymer free stents and is entirely silent as to the stent being "free from a biocompatible coating".

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-6, 8-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (WO 98/30255) in view of Shanley (Pub. No.: US 2002/0082680).

3. Kaplan teaches a stent comprising a releasable therapeutic agent comprising melatonin (col. 6 lines 5-18), the therapeutic agent being present in an effective amount to modify the healing response of the vessel wall after tissue injury (Kaplan discloses the use of melatonin to treat restenosis).

4. Kaplan fails to specifically describe the coating methods in applying the melatonin to the stent body, and thus lacks a coating directly on the surface of the stent which is free from a biocompatible coating. Shanley teaches direct loading of a therapeutic agent onto a stent as a known means of delivering therapeutic agent to the body (para, 73, stating: beneficial agent may be loaded into the openings alone if the agent is structurally viable without the need for a carrier). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the melatonin stent of Kaplan with direct loading in the absence of a polymer carrier as taught by Shanley for the purpose of maximizing the amount of therapeutic agent carried on the stent body.

5. The stent is a wire stent (see Kaplan, pg. 9 lines 2-10, noting that U.S. Pat. No.: 5342348 is a wire stent). The stent can form uniform thickness struts (see U.S. Pat. No.: 5342348).

6. Kaplan lacks recesses in the stent struts. Shanley teaches the use of recesses in stent struts for the purpose of delivering therapeutic agent to site of implantation (see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Kaplan with recesses as taught by Shanley for the purpose of delivering therapeutic agent. Such a modification of Kaplan would be a simple substitution of known drug delivery means, and would have occurred using known methods, yielding predictable results.

7. With respect to claims 8 and 9, Kaplan either lacks or does not specify the total load of melatonin or the time period for release of the melatonin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a total load of melatonin of at least .001μg/mm2 and a release for at least 6 hours, since both specified ranges would simply be an optimization of the disclosed drug combined with the disclosed stent of Kaplan. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

8. With respect to claim 15, the device of Kaplan in view of Shanely is fully capable of being a coronary endovascular stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774